K001985

JAN 2 5 2001

Safety and Effectiveness Information

Submitted By: April Lavender, RAC
Vice President, Regulatory Affairs
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, In 47402
(812) 339-2235

Device: Trade Name: IntroDeuce® Double Lumen Introducer
Proposed Classification Name: Catheter Introducer

Predicate Devices or Legally Marketed Devices:

Cook Intro Deuce™ Double Lumen Introducer	Marketed & Distributed by COOK INCORPORATED
Baxter Hemostasis Valve Introducer	Marketed & Distributed by Baxter Healthcare Corp.

Device Description

The IntroDeuce® Double Lumen Introducer consists of a flexible shaft connected to a rigid hub with two extensions and a proximal access site. The shaft has two lumens. The large lumen is accessible by both the large extension and the proximal access site. The small lumen is only accessible through the small extension and exits distally from the introducer tip. The proximal access site contains a hemostasis valve to prevent leakage.

Indications for Use

The IntroDeuce® Double Lumen Introducer is used to introduce balloon, electrode, closed or non-tapered end and other catheters. The second lumen allows venous pressure monitoring, blood sampling, and infusion of drugs and fluids. Supplied sterile in peel-open packages. Intended for one-time use.

Substantial Equivalence

The IntroDeuce® Double Lumen Introducer is similar to the Cook Intro Deuce™ Double Lumen Introducer and the Baxter Hemostasis Valve. The Cook Intro Deuce™ Double Lumen Introducer is a modification of devices manufactured and marketed by Cook prior to 1976 (Pre-Amendment A176790). The Baxter Hemostasis Valves were cleared under Premarket Notification number K981909. The similar indications for use and technological characteristics of the IntroDeuce® Double Lumen Introducer as compared to the predicate devices support a determination of substantial equivalency.

Test Data

The IntroDeuce® Double Lumen Introducer was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests include:

- Flow & Tensile Test
- Biocompatibility

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a percutaneous sheath.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2001

Ms. April Lavender
Vice President, Regulatory Affairs
COOK Incorporated
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402

Re: K001985
Trade Name: IntroDeuce® Double Lumen Introducer
Regulatory Class: II (two)
Product Code: DYB
Dated: October 25, 2000
Received: October 26, 2000

Dear Ms. Lavender:

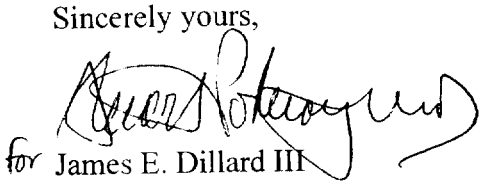
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001985

Device Name: IntroDeuce® Double Lumen Introducer

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COMPANY CONFIDENTIAL

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

Division of Cardiovascular Devices
510(k) Number # K001985